

Dockets Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane Room 1061 Rockville, MD 20852

Re: Prior Notice of Imported Food under the Public Health Security and Bioterrorism Preparedness Act of 2002; Notice of Proposed Rulemaking; Docket No. 02N-0278.

Comments of the Australian Dairy Corporation

Dear Sir or Madam:

The Australian Dairy Corporation (ADC) welcomes the opportunity to provide comments on the proposal of the Food and Drug Administration ("FDA") to implement sections 305 and 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("the Bioterrorism Act"). These sections provide for registration of food facilities and prior notice of imported food respectively.

The ADC among it activities provides trade policy services for the Australian Dairy Industry. The ADC is funded by a check-off on all farmers' milk production.

The FDA's proposed rule(s) require prior notification and establishment registration without documenting the level of protection sought by FDA or providing a risk assessment that justifies this level of protection. The ADC understands that the FDA also intends to substantively increase port inspection staff and laboratory capability.

The ADC notes that parts of the proposed rule(s) duplicate and conflict with rules under US Customs jurisdiction. Therefore the ADC is interested to learn of how these two sets of rules are to be harmonised to avoid conflict and duplication.

The ADC believes that the FDA is obliged, in accordance with the provisions of the SPS Agreement, to provide for the recognition of equivalence of exporting country measures. In this regard we urge the FDA to consult (and enter into negotiations) with the competent authority for food and related products, the Australian Quarantine and Inspection Service for the purposes of equivalence recognition.

Specific comments on the two dockets are attached. The ADC acknowledges the assistance of the Australian Quarantine and Inspection Service in preparing the attached documents.

OZN- OZ78

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Sincerely,

(Robert Pettit)

Robert Pettit

&

(Tim Martyn)

International Trade Development Group Australian Dairy Corporation

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